

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail Airbill No. EK 657 815 097US, in an envelope addressed to: Box Non-Fee Amendment, Commissioner for Patents, Washington, DC 20231, on the date shown below.

Dated: 6-24-02 Signature: Richard J. Zimmermann  
(Richard Zimmermann))



Docket No.:  
30105/32001

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

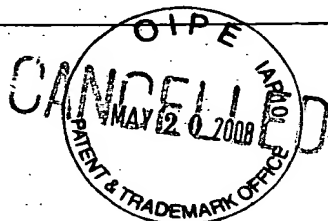
In re Application of:

Carl W. Hasting et al.

Application No.: 09/175,748

Filed: October 20, 1998

For: Performance-Enhancing Dietary Supplement



Group Art Unit: 1617

Examiner: R. Travis

### DECLARATION OF DAVID J. BARNES

I, David J. Barnes, am one of the named inventors of the application Serial No. 09/175,748, filed October 20, 1998, and assigned to Reliv' International, Inc. located in Chesterfield, Missouri. I have been employed by Reliv' International, Inc. since 1993, as Director of Research and Quality Control (from 1993 to 1995), as Director of Technical Affairs and Manufacturing Operations (from 1995 to 2001), and as Vice President of Technical Affairs and Manufacturing Operations (from 2001 to present).

As Vice President of Technical Affairs and Manufacturing Operations, I am directly involved and fully informed concerning the manufacturer of dietary supplements by Reliv' International, Inc. I have personal knowledge that the Provantage dietary supplement described in the examples of the above-identified patent application and claimed in that application was conceived, reduced to practice, finalized, cleared for commercial production, and approved for sale by the company long before August 21, 1998, the filing date of Gardiner Patent 6,136,339.

Submitted herewith are two groups of documents marked Applicants' Exhibit A and Applicants' Exhibit B, respectively. Certain information--particularly the names of suppliers--has been blanked out because it is considered confidential information. Otherwise, the documents are true copies of the originals.

The documents of Exhibit A (three sheets) set forth the formulation for Provantage. They constitute a QA Batch Test Record resulting in approval of the formulation on October 6, 1997 for commercial production of the dietary supplement constituting this invention.

The second group of documents (Exhibit B, four sheets) constitutes a collection of records relating to the subsequent commercial production and clearance of the dietary supplement disclosed and claimed in the application. They reveal that the product went into commercial production on October 7, 1997 and was packaged and approved for sale on that date.

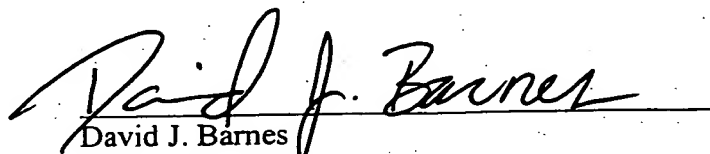
Since the Provantage product disclosed and claimed in the patent application was formulated, tested, approved, and commercially produced well before the filing date of Gardiner Patent 6,136,339, it follows that applicants' invention was completed, that is, conceived and reduced to practice, long before that filing date.

I have reviewed the Office Actions mailed June 20, 2001 and January 7, 2002, and I understand that the Examiner has rejected claims 11-14 and 25-27 as being anticipated by Gardiner Patent 6,136,339. I have reviewed that patent and respectfully submit that this declaration and the Exhibits appended hereto clearly establish that my co-inventors and I invented the subject matter of claims 11-14 and 25-27 prior to August 21, 1998 and, specifically, that my co-inventors and I invented a food supplement that includes both lipoic acid and creatine monohydrate long prior to the filing date of the Gardiner patent.

Application No.: 09/175,748

Docket No.: 30105/32001

I further declare that the foregoing statements are true to the best of my knowledge and belief. I am aware that willfully making false statements may subject me to punishment and may jeopardize the validity of any patent(s) that may issue on the pending application.



David J. Barnes  
253 Cove Landing Drive  
Wildwood, Missouri 63040

Dated: 6/19/02

TITLE Provantage #16 Final

Project No. \_\_\_\_\_

Book No. \_\_\_\_\_

8

From Page No. 69

objective : The Provantage formula #15 will be adjusted to accomodate for the increase in lecithin.

	<u>26g size x %</u>	<u>Grams</u>	<u>#16 Final %</u>
SuproFEXH100	61.8817	16.089	61.8808
A.A. Premix	2.6701	0.694	2.6692
Fructose	26.9723	2.034	27.0536
* Lecithin	2.00	0.520	2.000
Corti PS 20	0.3086	0.080	0.3077
* MCT PWD	1.8903	0.491	1.8885
Biopterine	0.0101	0.003	0.0115
Activin	0.1930	0.050	0.1923
COQ10	0.0302	0.008	0.0308
L-carnitine	0.2312	0.060	0.2308
Creatin Monohydrate	1.9262	0.501	1.9269
BBA Vanilla Flv. 1499	1.2064	0.314	1.2077
Art. Special Cpd.	0.5006	0.130	0.500
CLA (tonalin)	0.1005	0.026	0.100
Alpha lipoic Acid	0.0002	0.00005	0.0002
		26.00005	100%

\* increased lecithin to 2%

\* decreased MCT by 1%

ge No. 90

Witnessed &amp; Understood by me, \_\_\_\_\_

Date \_\_\_\_\_

Invented by \_\_\_\_\_

Date \_\_\_\_\_

Recorded by A. U.9-19-97

To Page No. \_\_\_\_\_

PENGAD - Bygonia, N.J.

APPLICANT'S  
EXHIBITA

MANUFACTURING WEIGH-OUT RECORD

RELIN

PROVANTAGE

SPEC. NO. 4040

BATCH NUMBER

BATCH SIZE (POUNDS)

ISSUED BY

DATE ISSUED

MASTER RECORD

APPROVAL

INITIALS

DATE

MFG.

R&D

O.A.

SPEC. NO.	STEP	INGREDIENT	POUNDS	SUPPLIER	LOT NO.	PARTIAL WT.	CONTAINER	WEIGHED BY	VERIFIED BY	BAGS @ (WT)	LOT NO.	STAGED BY	FULL	PARTIAL
7038	1	FRUCTOSE	405.81		CF70270174	5.81	4	ADS		8 @ 50	CF70270174			RR
7044	1	LECITHIN	30.00		97098102-2	30.00	5	BUL						RR
8835	1	CLA (TONALIN)	1.50		9706005	1.50	5	APL						RR
8810	1	SUPRO XT HO100	928.22		C64XK0002	2.12	7	ADS		21 @ (44.1)	* X R W 002 C6M 100			RR
8012	1	AMINO ACID PREMIX	40.04		F08092297	40.04	8	KM						RR
7130	1	CORTI PS 20	4.61		167379A	4.61	9	ADS						RR
8133	1	CREATINE MONOHYDRATE	28.91		10404282	28.91	9	KM						RR
8215	1	ART. SPECIAL COMPOUND (FRA.1)	7.50		3699729708	7.50	9	ADS						RR
8812	1	MCT POWDER	28.32		97-014-14	28.32	10	KM						RR
8060	1	BIOPERINE	0.17		2215	0.17	10	ADS						RR
8008	1	ACTIVIN	2.88		708002	2.88	10	KM						RR
8005	1	ALPHA LIPOIC ACID	0.003		101591-19	0.003	11	PKD						RR
7032	1	CO Q 10	0.47		7462	0.47	12	ADS						RR
7031	1	L-CARNITINE	3.47		970307	3.47	12	ADS						RR
7034	1	SBA VANILLA 14199	18.12		97074	18.12	12	ADS						RR
TOTALS			1500.00											

\* X R W 002

DATE WEIGHED	10/3/97	RR
TIME WEIGH-OUT STARTED	7:30 AM	RR
TIME WEIGH-OUT COMPLETED	7:55 AM	RR

O.A. DISPOSITION  
WEIGH-OUT SUPERVISOR

DATE	10-6-97	(APPROVE OR REJECT)
	RR	(RECORD COMPLETE)

QA Batch Test Record  
RELIV Products

Day Code 45061

Date 10.6.97

A = Acceptable  
U = Unacceptable

Product Peovantage

Shift 1

[illegible]

APPROVAL:

MFG  
R&D  
Q.A.

DATE  
6/4/43

6/4/93

6/4/97

REVISION 1

# Master Packaging Bill of Materials

Product: U.S. PROVANTAGE

Date: 10-7-97

Auditor:

Code: 45071/45061

## Operation and Standard Conformance

	Initials
All packaging removed from previous operation	CAW
Label conforms to standard	CAW

## Packaging Allocation Tracking

	Estimated Number
Number of labels allocated to job (based on 100% efficiency)	12,000 + 4,000 + 480 = 16,480
Label specification number	—
Number of labels used on salable product	15,762
Number of labels used on defective product	—
Number of labels destroyed during processing	167
Number of labels returned to storage	551

## Other Packaging For Job

	Size/ Number
Serving scoop size issued	70
	CC
401 x 411 cans conform to specification	✓
401 X 411 can bottoms conform to specification	✓

## Packaging Operation Data

Filling weight range (g) 401 x 411 can	290
Expiry date	—
Cans per case container	6

Q.A. approval :

Explain any unusual occurrences or discrepancies on the back of this record.

PSH000-000000, N.J.

APPLICANT'S  
EXHIBIT

3

Orig. 10/97

# CAN LINE

## START-UP & CHANGE OVER

### CHECKLIST

**\*\*MUST BE COMPLETED BEFORE START-UP AND CHANGE OVER\*\***

DATE: 10-2-97

DAY CODE: <sup>OKD 10-7-97</sup> ~~45071~~ 45061 ~~45071~~

PRODUCT: PROVantage

- ☒ CHECK CAN CODE FOR CORRECTNESS AND LEGIBILITY.
- ☒ CHECK AND CALIBRATE SCALE. TARE OUT CAN, APPROPRIATE SCOOP AND INSERT.
- ☒ VERIFY LABELS AND INSERTS.
- ☒ REMOVE ANY MATERIAL FROM THE AREA THAT IS NOT BEING USED (EX. LABELS, DIFFERENT SCOOP SIZES, INSERTS).
- ☒ CHECK CASE CODER FOR PRODUCT AND DAY CODE.
- ☒ ENSURE THAT PRODUCT IS RELEASED THROUGH QUALITY CONTROL. ALL TOTES MUST HAVE GREEN STICKER.

CHECKED BY:

Q.A.

SUPERVISOR

*Patty*  
*Cheryl / Cheryl*  
*Patty* \* 45071  
322



# PRODUCTION FILLING RECORD

DATE 10-7-97

SHIFT 1

DAY CODE ~~45061~~ 45071 KVV  
10/8/71

APPROVAL

MEG

## R&C

**Q.A**

DATE \_\_\_\_\_

1/20/97

120/97

1/20/97

[illegible]

6

9'000

**TOTAL BATCHES****TOTAL POUNDS**

# RELIV PRODUCTION TO WAREHOUSE RECORD

DATE 10-7-97

SHIFT 1

DAY CODE 45061 - 45071

APPROVAL

MFG

R&D

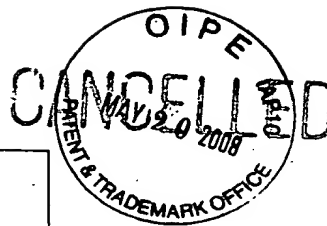
Q.A.

DATE 12/25/97

12/25/97

2/25/97

PRODUCT	LOT NUMBER	PALLET NUMBER	NUMBER OF CASES	TIME	TRANSFERRED BY (PRODUCTION)
Provantage	45061	100797-1	128	6:50	<i>[Signature]</i>
"	45061	100797-2	128	7:00	<i>[Signature]</i>
"	45061-45071	100797-3	128	7:55	TRR
"	45071	100797-4	128	8:15	RLM
"	45071	100797-5	128	8:23	RLM
"	45071	100797-6	128	9:08	RLM
"	45071	100797-7	128	9:20	RLM
"	45071	100797-8	128	9:38	RLM
"	45071	100797-9	128	10:12	RLM
"	45071	100797-10	128	10:20	RLM
"	45071	100797-11	128	10:37	RLM
"	45071	100797-12	128	11:37	RLM
"	45071	100797-13	128	12:00	RLM
"	45071	100797-14	128	12:18	RLM
"	45071	100797-15	128	12:27	RLM
"	45071	100797-16	128	12:42	RLM
"	45071	100797-17	128	12:54	RLM
"	45071	100797-18	128	1:34	RLM
"	45071	100797-19	128	1:45	RLM
"	45071	100797-20	128	2:03	RLM
"	45071	100797-21	62		



I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as Express Mail, Airbill No. EV323776436US, in an envelope addressed to: Mail Stop Patent Applications, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: 02/18/04

Signature: *[Signature]*

Docket No.: 30105/32001A  
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Carl W. Hastings et al.

(Continuation of U.S. Patent  
Application No.: 09/175,748  
Filed: October 20, 1998)



Group Art Unit: 1617

Examiner: R. Travers

For: Performance Enhancing Dietary Supplement

(SECOND) SUPPLEMENTAL DECLARATION OF DAVID J. BARNES

I, David J. Barnes, am the same person that signed and submitted a Declaration dated June 19, 2002 and filed in the Patent and Trademark Office by Express Mail on June 24, 2002, which is incorporated herein by reference, in the application to which the present application is a Continuation.

On page 2 of that Declaration, in Paragraph 2, it is stated that the ProVantage product embodying this invention "went into commercial production on October 7, 1997 and was packaged and approved for sale on that date."

Nowhere in such Declaration is it stated that such product was sold or offered for sale on October 7, 1997. The facts are that ProVantage was not sold, offered for sale, or publicly known until Saturday, October 25, 1997. On that date, the ProVantage product was unveiled in a meeting in San Francisco attended by distributors and potential distributors of Reliv' International's products.

The Rollout Meeting of October 25, 1997 had been planned weeks earlier at Reliv' International, as reflected in an internal memorandum dated September 17, 1997 and appended hereto as Exhibit 1. The memorandum was prepared by Kathy Blunt, a Marketing Coordinator for Reliv' International products, and outlines on page 2 the arrangements being planned for the unveiling of the ProVantage product scheduled for Saturday morning, October 25, 1997. The Saturday October 25 meeting, as so planned on September 17, 1997, occurred substantially as outlined in the memorandum and constituted the first public exposure and offer for sale of the ProVantage product.

The memorandum refers to a Press Release to be available on October 25, 1997, but in fact the Press Release did not go out until three days later. A copy of the Press Release dated October 28, 1997 is appended hereto as Exhibit 2.

Therefore, while my earlier Declaration correctly states that ProVantage went into commercial production on October 7, 1997, and was approved on that date for public sale, no sale or offer for sale occurred until the product rollout on October 25, 1997. Production began on October 7 to build inventory for sales to be made on and after the product unveiling that occurred on October 25, 1997, and all sales of the ProVantage product have been well within the one-year period preceding the application filing date of October 20, 1998.

I further declare that I am warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements and the like may jeopardize the validity of the application or any

patent(s) that may issue on the application, and I declare that all statements made of my own knowledge are true, and that all statements made on information and belief are believed to be true.



David J. Barnes  
253 Cove Landing Drive  
Wildwood, Missouri 63040

Dated: \_\_\_\_\_

2/3/84

## MEMO

TO: David Barnes  
Marilyn Bryant  
Martin Burks  
Arlene Doyle  
Don Gibbons  
Steve Hastings  
Dave Kreher  
Scott Montgomery  
Michelle Keefe  
Melanie Wolff

FROM: Kathy Blunt

DATE: 9/17/97

RE: Notes for today's ProVantage Rollout Meeting

---

SAN FRANCISCO

## Room Setup:

- Stage with pipe & drape
- Podium with mike
- Standing mike
- 2 lavilier mikes
- Slide projector with remote
- Screen
- Reliv banners
- Product Display
- Music before and after meetings
- Registration table - outside of room
- Water stations - outside of room

NOTE: Don to contact distributors to setup product display and take care of registration.

Don to provide an evening meeting outline

Martin to bring music.

Friday Night Meeting, October 24:

- Begin at 7:30 p.m., end at 9:00 p.m. – Opportunity Meeting
- Open doors at 7:00 p.m.
- Handout: Meeting agenda
- Bob & Carl to speak

NOTE: Kathy to bring Opportunity Slides.

Saturday Meeting, October 25:

- Room Setup:  
Same as Friday, with the addition of ProVantage banners & ProVantage product display (to be unveiled in the morning session)
- Morning Session: 9:00 a.m. to 11:30 a.m.
  - 9:30 a.m. Success Magazine – Don & Bob
  - 10:15 a.m. ProVantage – Dr. Carl & Dr. Ted
  - 11:30 a.m. Break
- Handouts:  
ProVantage Brochure  
Ad Slick  
Press Release
- Break 11:30 a.m. to 1:30 p.m.
  - T-shirts for sale
  - Order Entry open ready to take orders
- Afternoon Session: 1:30 p.m. to 3:30 p.m.
  - 2 Ambassadors, possibly Pinnock & Williams for a Plan of Action Session

Nationwide Call on Saturday October 25:

- Melanie to setup

## **NEWS RELEASE**

### **FOR FURTHER INFORMATION, CONTACT:**

David G. Kreher  
Chief Operating Officer  
(314) 537-9715

Fred A. Nielson  
Investor Relations  
(314) 537-9715

### **Reliv International Introduces New Soy-Based Sports Drink Targeting Functional Food and Sports Nutrition Markets**

#### **FOR IMMEDIATE RELEASE**

CHESTERFIELD, MO, October 28, 1997 -- Reliv International, Inc. (NASDAQ - RELV), an international manufacturer and network marketer of nutritional supplements and other products, has introduced a new fitness drink mix--ProVantage™ Performance Enhancer--featuring soy protein as a primary ingredient. The new product expands Reliv's presence in two fast-growing categories: functional foods and sports nutrition.

The exclusive ProVantage formulation combines soy protein and other nutrients in a powdered drink mix. Recent clinical studies have linked the incorporation of soy protein in the diet to health benefits such as increased energy, increased endurance, lean muscle mass, decreased length of recovery after exercise, and increased immune system function.

ProVantage is designed to offer consumers a convenient, healthy way to increase protein consumption. Two 8-ounce ProVantage shakes per day will provide a total of 28 grams of protein, primarily from soy. "This is an exciting addition for Reliv in a very promising market," said Robert L. Montgomery, Reliv Chairman, President and CEO. "We expect ProVantage to complement our existing line of nutritional supplements and functional foods. As such, it should generate significant interest in the marketplace, and a healthy level of incremental sales."

Since 1996, Reliv has introduced a total of three functional food products, most of which draw on the Company's extensive experience in soy protein.

--MORE--



Reliv International, Inc., based in suburban St. Louis, manufactures and distributes several lines of food products, including nutritional and fiber supplements, diet management products, functional foods, sports drink mixes and premium skin care products. The Company also provides blending, processing and packaging services for other companies' food products on a contract basis. Reliv International's common stock is traded on the Nasdaq National Market tier of The Nasdaq Stock Market under the symbol RELV.

###

Information contained in this release related to future sales should be considered forward looking and may be subject to the following risk factors, among others: acceptance of the products by distributors and customers, general sales trends and market conditions.



IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Application of: Carl W. Hastings et al  
Serial No. 09/175,748  
Filed 10/20/98

) Performance-Enhancing  
) Dietary Supplement  
)  
) Group Art Unit: 1617  
)  
) Examiner: R. Travers

Commissioner of Patents & Trademarks  
Washington, D.C. 20231

Sir:

REQUEST FOR INTERFERENCE WITH PATENT  
UNDER 37CFR §1.607

Applicants hereby request the declaration of an interference between this application and patent 6,136,339, granted October 24, 2000, to Paul T. Gardiner, for Food Supplements and Methods Comprising Lipoic Acid and Creatine.

Applicants propose the following counts for such interference:

Count 1. A food supplement, comprising lipoic acid or a derivative thereof, and creatine or a derivative thereof.

Count 2. A food supplement according to Count 1, comprising lipoic acid or a salt or ester thereof and creatine or a hydrate, salt or ester thereof.

Count 3. A food supplement according to Count 1, comprising lipoic acid or a derivative thereof and creatine monohydrate.

Count 4. A method for supplementing the diet of an athlete, comprising administering to the diet of the athlete a supplement comprising lipoic acid or a derivative thereof, and creatine or a derivative thereof.

Count 5. A method according to Count 4, wherein the food supplement is mixed with water to provide a liquid drink.

ATTACHMENT "C"

Serial No. 09/175,748

Count 6. A method for enhancing an athlete's muscle size or strength, comprising administering to the diet of the athlete a supplement comprising lipoic acid or a derivative thereof, and creatine or a derivative thereof.

Count 7. A food supplement according to Count 1, further comprising glutamine.

These proposed counts correspond exactly to Claims 1, 2, 3, 14, 24, 25 and 36 of patent 6,136,339 except that the term "count" has been substituted for "claim" in the dependent claims.

In a Preliminary Amendment filed herewith, applicants submit a new set of claims to be substituted for the original claims. Of that set, new Claims 11-14 and 25-27 correspond directly to proposed Counts 1-7, except that the term "claim" rather than "count" appears in the dependent claims.

All of the claims set forth in the preliminary amendment, as well as all of the claims originally presented in this application, call for a food supplement that includes both lipoic acid, specifically alpha lipoic acid, and creatine monohydrate. As an essential ingredient, alpha lipoic acid is indicated as being a potent free radical scavenger and chelator of toxic metals (specification, page 4). It is a coenzyme that participates in converting blood sugar into energy and, in addition, is identified as an antioxidant nutrient that networks with other antioxidants in quenching free radicals (page 11). It is understood that the other antioxidant nutrients function more effectively when there is more of the lipoic acid available than what is tied up in use by

Serial No. 09/175,748

the body as a coenzyme. As stated on page 11, lipoic acid is easily absorbed and is readily bioavailable.

As an essential ingredient in applicants' supplement, creatine is described as helping to reduce muscle fatigue and rebuild lean muscle mass (pages 3,4). On pages 8 and 9, it is explained that energy consumed by muscles is largely in the form of adenosine triphosphate (ATP) and that during short-term, high-intensity exercise the demand by working muscles for ATP increases to several hundred times the requirement of muscles at rest. Since ATP can be stored only to a limited extent in muscle cells, maintaining peak performance requires constant replenishment of ATP levels. The primary resupplier of ATP levels for short-duration, high-intensity exercise is the amino acid creatine, about 60% of which is stored in skeletal muscle tissue in the form of creatine phosphate. During muscle contraction, creatine phosphate converts to adenosine triphosphate (ADP) to ATP, thereby replacing the ATP consumed during exercise.

As stated on page 9, neither creatine phosphate nor ATP can be directly supplemented in the diet; however, higher levels of creatine may be derived from creatine monohydrate, a form of creatine which has been shown to raise total plasma levels of creatine. Creatine monohydrate in applicants' dietary supplement shortens the time necessary for the body to generate replacement creatine phosphate and thus significantly reduce muscle recovery time between short-duration, high-intensity activities.

Applicants' Claim 14 also calls for the presence of glutamine. As brought out on page 6, glutamine is known to

Serial No. 09/175,748

promote anabolic conditions in muscle cells and to increase the rate of protein synthesis. It indirectly promotes growth by increasing the hydration state of muscle cells. When cells are swollen with water, the breakdown of protein, glycogen and glucose is inhibited. Glutamine stimulates protein and glycogen synthesis. Conversely, if a cell becomes dehydrated, it shrinks and immediately goes into a catabolic state that breaks down the muscle's vital proteins.

Other composition claims presented in the Preliminary Amendment sets forth other ingredients believed to be critical in applicants' dietary supplement.

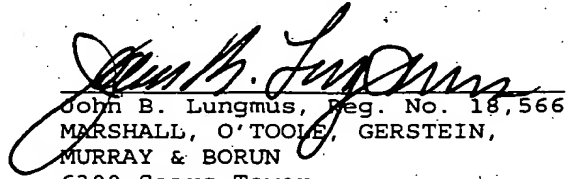
New method Claims 25, 26 and 27 find support throughout applicants' disclosure, since that disclosure is concerned in its entirety with a dietary supplement to be orally ingested for enhancing physical performance of human subjects. Essential ingredients in such a dietary supplement are lipoic acid, particularly alpha lipoic acid, and creatine, particularly creatine monohydrate. As stated on page 14, the dietary supplement takes the form of a fine powder that is to be consumed as a beverage, with one to three scoops of the powder (26g to 78g) being mixed with water, juice, milk or any other suitable beverage.

It is to be noted that the effective filing date of applicants' application (October 20, 1998) is less than three months after the filing date of patent 6,136,339 (August 21, 1998). It is therefore submitted that applicants have made a prima facie showing under 37 CFR 1.608(a).

Serial No. 09/175,748

Pursuant to 37 CFR 1.608(a), applicants, by their attorney, state that there is a basis upon which applicants are entitled to a judgment relative to the patentee. Accordingly, it is respectfully requested that an interference be declared between this application and patent 6,136,339.

Respectfully submitted

  
John B. Lungmus, Reg. No. 18,566  
MARSHALL, O'TOOLE, GERSTEIN,  
MURRAY & BORUN  
6300 Sears Tower  
233 South Wacker Drive  
Chicago, Illinois 60606-6402  
(312) 474-6300